UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,470	09/23/2003	Rajeev A. Jain	029318-0972	9048

31049 7590 07/27/2010

Elan Drug Delivery, Inc. c/o Foley & Lardner
3000 K Street, N.W.
Suite 500
Washington, DC 20007-5109

EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,470	JAIN ET AL.	
	Examiner	Art Unit	
	Brian-Yong S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-50, 54-106 and 110-111* is/are pending in the application.

4a) Of the above claim(s) *54-86,110 and 111* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-50 and 87-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/13/10, 06/14/10, 04/28/10, 11/13/09* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicant's response filed on 04/28/2010. Claims 27 and 28 and 87 have been amended. Claim 27-50, 54-106 and 110-111 are currently pending in the application, but claims 54-86 and 110-111 were withdrawn from consideration as being drawn to the non-elected invention. Claims 27-50 and 87-106 are currently pending for prosecution on the merits of the instant application.

2. Applicant's amendment which requires "porous" necessitates a new ground of rejection in this Office Action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 27-35, 37-50, 87-94, 96-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Straub et al. (US 6395300).

Straub teaches a solid oral dose form pharmaceutical composition comprising "poorly soluble" active drugs (e.g., NSAIDs such as naproxen) in a porous matrix form to enhance their rate of dissolution, dissolved in a pharmaceutically acceptable water-soluble or water-dispersible excipients such as water soluble polymers (e.g., polyethylene glycol, polyvinyl pyrrolidone, polyethylene oxide, gelatin, starch, acacia, xanthan gum, etc…) or sugars (e.g., mannitol, lactose, sorbitol, xylitol, erythritol, etc…), wetting agents such as surfactants (e.g., gelatin, gum acacia, polyethylene glycols, polyoxypropylene copolymers, polyethyleneoxide, etc…), tonicity agents (e.g., mannitol, sucrose, etc…) and solid pore form agent or effervescent (e.g., ammonium bicarbonate), wherein the average particle size of the active is between about 100 nm and 5μm and the dispersion is sprayed dried, optionally followed by lyophilization, fluid bed drying (or fluid bed granulation) or vacuum drying and wherein the matrix can be further processed using standard techniques into tablets or capsules for oral administrations (column 2, lines 15-56; column 8, line 32 through column 10, line 49; column 10, line 54 through column 11, line 46; Example 7; Claims); the concentration of the active is in range from at least 1 to 95%, preferably at least about 10%, and more preferably between about 10 and 60% (column 3, line 41 through column 4, line 37); the concentration of the excipient is in range of less than about 95%, more preferably less than about 80% (column 8, lines 22-32); and the drug present in the solids or powder produced is in a crystalline or an amorphous state (column 12, lines 42-45).

With respect to "the solid dose matrix surrounding the nanoparticulate active agent and at least one surface stabilizer disintergrates or dissolves upon contact with saliva is less than about 3 minutes", such property or characteristic deems to be inherent to the referenced porous drug matrix composition since the essential components of Straub are identical to the instant composition (that is an oral solid dose rapidly disintegrating nanoprticulate having an average particle size of less than 1000nm and water-dispersible excipient). See Figures, particularly Fig. 4). Thus, Straub anticipates the instant invention.

With respect to the specific average particle sizes, the referenced average particle size of the active, e.g., less than about 1000 nm, preferably less than 300nm, more preferably 200nm, "metes and bounds" the instantly required particle size and thus anticipates the claimed invention.

With respect to the specific amounts of active agent or excipient in said composition, the referenced concentration of the active agent which is in range from about 0.1 to 60% and the referenced concentration of polyvinylpyrrolidone which is in range from about 0.1 to about 90% "metes and bounds" the instantly required amounts of active and/or excipients and thus anticipates the claimed invention.

With respect to "said excipient is selected from the group consisting of a direct compression material and a non-direct compression material", such property or characteristic deems to be inherent to the referenced excipients such as mannitol. Thus, Eickhoff anticipates the instant invention.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to

believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 36 and 95 are rejected under 35 U.S.C. 102(e) as being anticipated by Straub et al. (US 6395300).

The teaching of Straub has been discussed in above 35 USC 102(e) rejection.

The teaching of Straub differs from the instant invention in the specific average particle size of the active agent, namely less than about 50 nm.

However, one having ordinary skill in the art would have expected at the time of the invention was made that the specific average particle size of the active agent of the instant claims would have been characteristic of the modified prior art method. Generally, differences in the average particle size will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such particle distribution concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it not inventive to discover the optimum or workable particle average particle size by routine experimentation.

5. Claims 27-50 and 87-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eickhoff et al. (USP 5518738) in view of Straub et al. (US 6395300), and further in view of applicant's admitted prior art of record (pages 1, line 31 through page 4, line 22) or Acosta-Cuello (WO 97/18796 A1).

Eickhoff teaches a rapidly-acting ("more rapid onset of action") solid oral dose form pharmaceutical composition comprising "poorly soluble" active drugs in nanoparticulate form, for example anti-inflammatory agent such as NSAIDs in crystalline phase and nanoparticulate, dispersed in mixtures of hydroscopic sugar (i.e., mannitol), polyvinylpyrrolidone and sodium

lauryl sulfate, wherein the polyvinylpyrrolidone surface modifier mixed with the hygroscopic sugar and sodium lauryl sulfate is adsorbed on the surface of the active drug (abstract; column 2, lines 41-50; column line 59 through column 3, line 32; column 3, lines 36-48; column 5, lines 45-52; claims 1-10 and 15; claims 1-10, particularly claim 4), wherein the average particle size of the active is less than about 1000 nm, preferably less than 300nm (column 3, lines 49-59); the concentration of the active is in range from about 0.1 to 60% (column 4, lines 16-21; the concentration of polyvinylpyrrolidone is in range from about 0.1 to about 90% (column 4, lines 21-24 and column 5, lines 42-44); the concentration of the hydrogroscopic sugar (i.e., mannitol) in range of from 10 to 75% (column 5, lines 53-54); and the concentration of the sodium lauryl sulfate is in range of from 0.1 to 10% (column 5, lines 55-57); and the dispersion is sprayed dried to a fine powder in a fluidized bed coater or the final composition is prepared in caplets (Examples). Eickhoff also discloses a method of treating a mammal comprising administering said composition (see claims 11-14). However, Eickhoff is silent about the preparation of said composition into matrix or porous matrix form.

The teaching of Straub has been discussed in above 35 USC 102(e) rejection.

Applicant's admitted prior art of record and WO'796 are provided as supplemental references to demonstrate the routine knowledge in preparing micro- or nano-particulate compositions in a rapidly disintegrating or dissolving or fast-melting solid oral dose or matrix form (see particularly page 1, line 31 through page 4, line 22 of the instant specification; abstract, page 5, lines 19 through page 6, line 5 of WO'796).

As discussed above, Eickhoff's formulation differs from the instant invention mainly in the preparation of said composition into porous matrix form where said matrix "rapidly disintegrates upon contact with saliva in less than three minutes" recited in claim 87.

However, such determination of appropriate matrix or porous matrix form having rapidly disintegrating dosage form upon contact with saliva in less than about 3 minutes for treatment involving each of the above mentioned formulations would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the known dosage formulation art (for example Straub, the applicant's admitted prior art and/or WO'796).

As evidenced by the applicant's Straub, admitted prior art and/or WO'796, there are general references indicating that pharmaceuticals generally may be formulated and delivered matrix or porous matrix rapidly dissolving formulations, as well as disclosing benefits to be achieved by "rapidly dissolving formulation" or "fast melt" dosage forms versus other modes of administration. Therefore, there exist general art accepted motivations for formulating drugs for matrix or porous matrix "rapidly dissolving formulation" or "fast melt" dosage forms.

Alternatively, one having ordinary skill in the art would have been motivated to modify the teaching of Eickhoff in light of Straub to increase the dissolution rate of the drug by increasing the surface area of the drug available to contact the aqueous media at the site of administration or site of absorption.

With respect to the preparation of said composition via lyophilization, applicant's admitted prior art of record (particularly page 3, lines 13-22) teaches the routine knowledge in preparing fast disintegrating oral dosage form or fast melt dosage formulation via free-drying

techniques. Above references in combination make clear that the preparing said rapidly disintegrating or dissolving dosage formulation or fast melt dosage forms made by various techniques including fluid bed granulation or lyophilzation is well known and within the skill of artisan. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 27-50 and 87-106 are rejected under the judicially created doctrine of double patenting over claims 1-16 and 21 of USP 6165506, further in view of the applicant's admitted prior art of record (page 3, lines 13-22) or Straub et al. (US 6395300).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent are directed to a oral solid dose nanoparticulate formulation comprising water-soluble or water-dispersible excipient and a poorly

soluble active agent less than about 200 nm prior to inclusion in the dosage forms and at least one surface stabilizer.

Since the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps, the inclusion of alkali agent to increase the dissolution rate of nanoparticulate naproxen disclosed in US'506 falls within the scope of the invention and makes obvious the instant invention.

Although USP'506 is silent about the characteristic of said composition having "rapidly disintegrating", such property or characteristic deems to be inherent to the referenced composition since the essential components of USP'506 are identical to the instant composition. Thus, USP'506 makes obvious the instant invention.

With respect to the preparation of said solid dose to porous matrix, such determination of appropriate matrix or porous matrix having rapidly disintegrating dosage form upon contact with saliva in less than about 3 minutes for treatment involving each of the above mentioned formulations would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the known dosage formulation art (for example Straub and/or the applicant's admitted prior art).

As evidenced by the applicant's Straub and/or admitted prior art, there are general references indicating that pharmaceuticals generally may be formulated and delivered matrix or porous matrix rapidly dissolving formulations, as well as disclosing benefits to be achieved by "rapidly dissolving formulation" or "fast melt" dosage forms versus other modes of

administration. Therefore, there exist general art accepted motivations for formulating drugs for matrix or porous matrix "rapidly dissolving formulation" or "fast melt" dosage forms.

6. Claims 27-50 and 87-106 are rejected under the judicially created doctrine of double patenting over claims 1-177 of US 7276249, and further in view of applicant's admitted prior art of record (pages 1, line 31 through page 4, line 22), Kerkhof et al. (WO 01/45674 A1) or Straub et al. (US 6395300).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant invention overlaps with the patented claims.

Although independent claims of 1, 64, 121, 178 and 184 of US'249 do not specially recite the instant "at least one pharmaceutically acceptable water soluble or water-dispersible excipient", it is clear from reading the referenced claims 42-50, 56, 99-103, 105-113, 118, 156-160, 162-170 and 175 that said composition is prepared in the water soluble or dispersible excipients. Thus, US'249 makes obvious the instant invention.

With respect to the instantly required rapidly disintegrating or dissolving property of said composition in claim 87, such determination of suitable dosage delivery form is considered obvious task for the skilled artisan especially in view of the referenced claim 34, .97 and 154. Thus, USP'249 makes obvious the instant invention.

With respect to the instantly required specific nanoparticle sizes of the active drug and the specific amounts of active and inactive ingredients in claims 91-101, such optimization of known active and/or inactive ingredients is considered obvious task for the skilled artisan

especially in view of the referenced claims 11-24, 26-29, 74-92, 114-115 and 131-149. Thus, USP'249 makes obvious the instant invention.

With respect to the preparation of said composition via "spray-dried mannitol and spray-dried lactose", "fluid bed granulation" or "lyophilized" or the preparation of said composition with "a direct compression material and a non-direct compression material", namely mannitol or lactose and effervescent agent, such determination of suitable technique to make "fast melt" or 'rapidly disintegrating or dissolving" drug or using known secondary ingredients in is considered obvious task for the skilled artisan especially in view of the referenced claims 34-35, 97-98 and 154-155 and applicant's admitted prior art of record (pages 1, line 31 through page 4, line 22) or Kerkhof et al. (WO 01/45674 A1). Thus, USP'249 makes obvious the instant invention.

With respect to the preparation of said solid dose to porous matrix, such determination of appropriate matrix or porous matrix having rapidly disintegrating dosage form upon contact with saliva in less than about 3 minutes for treatment involving each of the above mentioned formulations would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the known dosage formulation art (for example Straub, Kerkhof et al and the applicant's admitted prior art).

As evidenced by the applicant's Straub, Kerkhof et al and/or admitted prior art, there are general references indicating that pharmaceuticals generally may be formulated and delivered matrix or porous matrix rapidly dissolving formulations, as well as disclosing benefits to be achieved by "rapidly dissolving formulation" or "fast melt" dosage forms versus other modes of

administration. Therefore, there exist general art accepted motivations for formulating drugs for matrix or porous matrix "rapidly dissolving formulation" or "fast melt" dosage forms.

In looking in continuity data, it is noted that applicant has numerous issued patent and pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, 09/337675, 11/275069, 10/392303, 12/068706, etc… are drawn to same or similar subject matter(s).

Response to Arguments

7. Applicant's arguments and exhibits filed 04/28/10 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the position that the instantly claimed rapidly disintegrating dosage form comprising a nanoparticulate active agent was not available at the time of the invention was made.

This argument is not found persuasive. Contrary to the applicant's argument, Straub clearly teaches the rapidly disintegrating porous matrix solid dosage from of a nanoparticulate active drug. Thus, the instant invention is anticipated by Starub or obvious over the cited references in combination above.

In response to the applicant's argument that one skilled in the art would not have considered "it obvious to combine rapidly disintegrating technology with nanotechnology

because the former applies a taste-masking coating which decreases dissolution of drugs in general; whereas the latter aims at increasing dissolution of drugs by reducing the particle size", the examiner recognizes that taste-masking technique such as film coating technique is not necessarily implemented in the preparation of a rapidly disintegrating or dissolving or "fast melt" dosage forms. For instance, WO'796 discloses fast-melt solid dosage form where no film coating technique is utilized to improve aftertaste. Accordingly, the examiner determines that the proferred evidence is not sufficient to overcome the rejection on the record.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. No Claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614